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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------------|------------------|
| 10/541,786  | 08/29/2006  | Barry Douglas Moore  | 031749/295113                 | 4147             |
| 826 7590 01/29/2011<br>ALSTON & BIRD LLP<br>BANK OF AMERICA PLAZA<br>101 SOUTH TRYON STREET, SUITE 4000<br>CHARLOTTE, NC 28280-4000 |             |                      | EXAMINER<br>YOUNG, MICAH PAUL |                  |
|   |             |                      | ART UNIT                      | PAPER NUMBER     |
|   |             |                      | 1618                          |                  |
|   |             |                      | MAIL DATE                     | DELIVERY MODE    |
|   |             |                      | 01/20/2011                    | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/541,786

**Applicant(s)**

MOORE ET AL.

**Examiner**

MICAH-PAUL YOUNG

**Art Unit**

1618

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 100-136 is/are pending in the application.
- 4a) Of the above claim(s) 112-136 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 100-111 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-945)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7/11/05, 8/29/06, 2/05/10
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Information Disclosure Statement**

The information disclosure statement (IDS) submitted on 7/11/05, 8/29/06 and 2/5/10 were filed in a timely manner. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 101 and 103 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*,

86 USPQ 481 (Bd. App. 1949). In the present instance, claim 101 recites the broad recitation between 5 and 100%, and the claim also recites between about 20 and 80% which is the narrower statement of the range/limitation. In the present instance, claim 103 recites the broad recitation between less than about 30 vol%, and the claim also recites less than about 10-20 vol% and less than about 8 vol% which is the narrower statement of the range/limitation.

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 100-111 are rejected under 35 U.S.C. 102(b) as being anticipated by Thanoo et al (USPN 5,945,126 hereafter '126).

The '126 patent teaches a continuous method of forming particles comprising the following steps: providing a stream of an aqueous solution comprising a coprecipitant molecule and an active agent, and rapidly mixing the stream with a greater volume of another continuous stream of an organic solvent (Examples). The solvent can be removed if desired, but is optional (Example 1 and 2). The solvent include water, menthol, ethanol and other organic solvents (col. 4, lin. 50-60). The aqueous phase comprises a bioactive agent including peptide drugs, proteinaceous drugs, steroidal drugs and non-steroidal drugs (col. 4, lin. 30-48). The bioactive agents include albumin (Example 6). Leuprolide a preferred molecule has a molecular weight of below 4kDa. The solution comprises methylene chloride with a molecular weight of 84.93 and

is less soluble in water (Example 2). After the bioactive agent/methylene chloride solution is admixed continuously with the stabilizing solvent solution, microspheres are formed of the bioactive agent (Example 2). The resultant particles have a drug load of at least 9.88% with residual methylene chloride (Examples 1). This concentration would at least meet the limitation of claim 101. The two streams are pumped into a mixing vessel where the continuous streams are agitated with turbulent fans (Figures). The two streams are flowed at different rates, with the solvent mixture slower than the aqueous stream, this allows for more control over the size and shape of the particles (col. 2, lin. 40-53). The particles are formed substantially instantaneously in less than 3 seconds during the continuous process (col. 11, lin. 53-65). Upon mixing the particles comprise both the bioactive agent and the coprecipitant molecules, thus the components are precipitated out together (col. 4, lin. 25-35; Example 7, claims). The process comprises water, yet the final product is silent to the water content (Examples 1-7). It is the position of the Examiner that the water is removed meaning the water content is less than 8 vol%, meeting the limitations of claim 103.

Claims 110 and 111 are drawn to particles formed by the method of claim 100, render the claim product-by-process claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In the instant case, the method of the ‘126 patent produces particles comprising bioactive molecules and coprecipitant molecules with

molecular weight under 4kDa. The particles further comprise stabilizers with high melting points that would raise the melting point of the particle above 90<sup>0</sup>C. For these reasons the claims are anticipated.

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Thursday 7:00-5:30; every Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/  
Examiner, Art Unit 1618

